



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,863	12/16/2003	Robert Emmett Atkinson	AEWI-I	5348
34485 7590 02/20/2009 ROBERT E. ATKINSON, PC 2679 RIVIERA DRIVE SOUTH WHITE BEAR LAKE, MN 55110				
EXAMINER				
KAHELIN, MICHAEL WILLIAM				
ART UNIT		PAPER NUMBER		
3762				
MAIL DATE		DELIVERY MODE		
02/20/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/736,863

Applicant(s)

ATKINSON ET AL.

Examiner

MICHAEL KAHLIN

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29, 30, 32, 34-36, 38, 40-44 and 46-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29, 30, 32, 34-36, 38, 40-44 and 46-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
3. Claims 29, 30, 32, 34-36, 38, 40-44, and 46-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osypka (US 6,738,674, hereinafter "Osypka") in view of Huepenbecker et al. (US 6,289,251, hereinafter "Huepenbecker").
4. In regards to claims 29, 34, 35, 41, and 43, Osypka discloses the essential features of the claimed invention including an electrical lead (312) with a lumen extending therethrough (Fig. 7) and a distal exit port distal of the one or more distal electrodes (322a and 322b); and an anchoring device (Fig. 11) including a self-expanding anchor (60) and an elongate tether comprising a polymeric cord (14)

extending proximally from the anchor, extending through the proximal entry port of the lead (Fig. 7), and wherein the tether is longitudinally movable in the lumen of the lead such that the lead may be advanced over the tether (Fig. 9). Osypka does not disclose that the tether is tied by knot or swaged to the anchor. Huepenbecker teaches attaching anchors to tethers by tying by knot or swaging (col. 4, lines 19-26) to provide the predictable result of securely fixing an anchor with conventional means. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Osypka's invention by attaching the anchor to the tether by tying by knot or swaging to provide the predictable result of securely fixing an anchor with conventional means.

5. In regards to claims 30, 36, and 42, Osypka discloses a connector for limiting longitudinal movement between the lead and anchoring device (col. 7, lines 2-6; by limiting movement between the tether and anchor, movement is limited between the lead and anchor), and is insertable into the lead before the tether is deployed.

6. In regards to claims 40 and 46, the tether is detachable from the lead using, e.g., scissors or wire cutters.

7. In regards to claims 47-49, the lead is an implantable pacing lead (col. 1, line 15). In regards to claims 32, 38, and 44, Osypka's modified invention discloses the essential features of the claimed invention except for a tether that comprises a braid. It is well known in the pacing arts to provide tethers, such as Osypka's, with braids, such as braided conductors, to provide the predictable results of strong and flexible lead elements that resist breaking. Therefore, it would have been obvious to one having

ordinary skill in the art at the time the invention was made to further modify Osypka's invention by providing a tether comprising a braid to provide the predictable results of strong and flexible lead elements that resist breaking.

Response to Arguments

8. Applicant's arguments filed 1/8/2009 have been fully considered but they are not persuasive. Applicant argued that Osypka fails to disclose a polymeric cord, and provided a dictionary definition of cord ("a: a long slender flexible material usually consisting of several strands (as of thread or yarn) woven or twisted together b: the hangman's rope"). However, the Examiner respectfully disagrees that this definition controls, and even if this particular definition of "cord" did control, Osypka's invention reasonably reads on this definition. Although the supplied definition is a plain meaning of "cord," the Office is required to impart the *broadest reasonable* plain meaning to claim terms. See MPEP 2111. As such, the Examiner is also considering the plain meaning of "cord" to include electrical "cords," such as the term is used to describe e.g., household extension cords or cords that connect lamps to electrical receptacles. Osypka's element 14 falls within this definition. Further, Applicant's broad conclusory statement that "[c]learly the Osypka lead is not the same as a tether" renders it unclear as to what aspect of the supplied definition of "cord" is inconsistent Osypka's invention. The Examiner is assuming that Applicant is referring to a requirement that a "cord" consist of several strands (because Osypka's element 14 is clearly a long slender flexible material). However, even the supplied definition of "cord" indicates that this

usage of the term refers to structures that *usually* consist of several strands, and thus contemplating some "cords" which do *not* have several strands.

9. Applicant further argued that modifying Osypka by tying the lead 14 (or outer jacket) of Osypka would result in a large knot that would render the device inoperable, and thus tying Osypka's lead into a knot is contrary to the teachings of the reference. However, the claim language does not require that the tether itself be tied into a knot, but merely that the tether is *tied by a knot* to the anchor. For instance, a boat can be *tied by knot* to a dock without the boat itself being tied into a knot. Similarly, the teaching of Huepenbecker (Fig. 4) contemplates an anchor *tied by knot* (via element 50; col. 4, lines 19-25) to a tether/lead that does not require any sort of tying of the lead/tether itself. The examiner maintains that providing a similar sort of anchor attachment means to Osypka's invention would have been *prima facie* obvious at the time of invention, as detailed above.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Examiner, Art Unit 3762

Application/Control Number: 10/736,863

Page 7

Art Unit: 3762

/Angela D Sykes/

Supervisory Patent Examiner, Art Unit 3762